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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/092,546 06/05/98 KINDLER

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QM32/0608

EXAMINER

THOMPSON, M

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

06/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/092,546

Applicant(s)

KINDLER ET AL.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03-19-01.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-14,19,22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 15-18, and 20-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 1998 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the Species election in Paper No. 14 is acknowledged. The traversal is on the ground(s) that claims 1 and 17 are generic and since each of the claims include a generic and broad valve the election is improper. This is not found persuasive because while the Examiner agrees that the generic claims include a valve, the different and modified embodiments are the species in which the Examiner has required Applicant to elect. The Examiner accepts Applicants arguments with respect to claims 1 and 17 being sufficiently generic. Therefore upon allowance of the generic claims Applicant will have the opportunity to request a rejoinder of all the species depending from claims 1 and 17.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 10-14, 19, and 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no **allowable** generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12 and 14.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "wall" of claim 8 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Specification

5. The disclosure is objected to because of the following informalities: The disclosure appears to fail in teaching method in which the valve/disk of claim 21 as preventing back-flow as taught by Applicant's invention. The Examiner is unclear if Applicant has intended to claim such a valve/disk.

Appropriate correction is required.

Claim Objections

6. Claim 21 is objected to because of the following informalities: It is unclear how the valve/disk of claim 21 prevents the back-flow of fluid into the container since it appears that Applicant teaches a device which prevents back-flow in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner what "wall" Applicant is referring to in the claim or specification. (feed line 13, page 10?)

Claim Rejections - 35 U.S.C. §102/103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Michel et al. ('874). Michel et al. teaches a device for the metered administration of a fluid comprising a container having a piston for administering fluid through an outlet, a catheter connected to the outlet of the container having a front end and an injection needle. (see figure 3) He teaches a

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valve positioned between the outlet and injection needle (58 column 5,6; lines 60-68 and 1-6 respectively), the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug a phenomenon common to all syringe type devices with a piston.

13. Claims 2, and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michel et al. ('874) in view of Paradis ('097). Michel et al. teaches all of the limitations of the claims to include a valve for controlling flow, however, he fails in specifically stating the type of valve being utilized in the invention, a valve body that is sealingly encloses the aperture in response to pressure, tensioned over a sealing lip at the feed line. Paradis teaches a valve body that is passive in nature, having a valve body that is sealingly encloses the aperture in response to pressure, tensioned over a sealing lip at the feed line. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the valve of Michel et al. with a the passive valve of Paradis to simply substitute one valve for another since both elements were art recognized equivalents at the time the invention was made, and one of ordinary skill would have found it obvious to substitute one valve for another.

14. Claims 17-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boettger ('244) in view of Paradis ('097). Boettger teaches a device for the metered administration of a fluid comprising an ampoule having a piston for administering fluid through an outlet, a catheter connected to the outlet of the container having a front end and an injection needle. (see figure 1 and figure 14) He teaches a valve positioned in the housing between the outlet and injection needle (18/20 composed of figure 14), the valve having an inlet and outlet

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end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Please note the Brief Description of the figures when interpreting the embodiments of Boettger. Also note that with respect to claim 21 there are several examples of valves that exhibit circular disks with openings etc. However it appears that claim 21 would allow for fluid to pass back into the container as addressed in the objections indicated above.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Response to Arguments

16. Applicant's arguments with respect to claims 1, 2, 6-9, 15-18, and 20-21 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

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Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

Any questions pertaining to informal matters such as the status of a case, missing portions of an Office Action, references, filing, paper matching, etc., should be directed to the Examiner's Legal Instruments Examiner (LIE), Rosalind Smith, at (703) 305-2440.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Anh Tuan Nguyen, can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

Michael M. Thompson

Patent Examiner

MT 

June 3, 2001


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

8/4/01